

**REMARKS/ARGUMENTS**

**A. Summary of the Amendment**

Reexamination and reconsideration are courteously requested. By way of the present amendment, the specification and drawings are amended. Further, claims 1, 11 to 13, 16, 20, and 24 are amended. No claims are added or canceled. Thus, claims 1 to 24 remain pending for the Examiner's consideration, with claims 1, 13, and 20 being independent claims.

**B. Objections to the Drawings**

The Examiner objected to Figures 1 to 4, and 10 for failing to comply with certain rules and formalities. In response, replacement sheets 1/5, 2/5, and 5/5 are filed herewith and include changes to Figs. 1 to 4, and 10. In Figs. 1 to 4, the phrase "Prior Art" is added. In Fig. 2, the reference (100) is changed to (100'). In Fig. 4, the reference (310) is removed. In Fig. 10, previously omitted reference (60) has been added to label a guidewire removal tool. These changes are believed to address and overcome each of the objections set forth by the Examiner.

**C. Objections to the Specification**

The specification is objected to for various typographical errors. The present amendment to paragraphs 34, 37, and 44 of the specification are believed to address and overcome each of the objections set forth by the Examiner.

**D. Objections to the Claims**

Claims 13 to 19, and 24 are objected to for various informalities. The present amendments to each of these claims is believed to address and overcome each of the objections set forth by the Examiner.

**E. Rejections Under 35 U.S.C. §§ 102, 103**

Claim 20 is rejected as being anticipated by U.S. Patent No. 6,660,515 (Windheuser). This rejection is respectfully traversed. Claim 20 as filed recites a catheter shaft having a first lumen that is sized to receive a guidewire, and a guideway providing transverse access from the catheter shaft exterior to the first lumen. Importantly, both the first lumen and the guideway extend the entire shaft length, or more particularly, from the shaft proximal end to the shaft distal end. Windheuser discloses a catheter 34 that has a U-shaped channel 42 that is sized to

receive a guidewire 36, and a guideway (sides of the U-shape) that provides transverse access from the catheter shaft exterior to the U-shaped channel. However, the guideway has proximal and distal ends 52 and 54 that do not extend the entire length of the catheter shaft 38. FIG. 1 clearly depicts the guideway only extending along an intermediate portion of the catheter shaft 38. For this reason, claim 20 is not anticipated by Windheuser.

Claims 20 to 21 are rejected as being anticipated by U.S. Patent No. 4,601,713 (Fuqua). The Examiner particularly references the catheter depicted in FIGs. 11 and 12 as anticipating these claims. These rejections are traversed in view of both the claims as originally filed and as currently amended. Fuqua discloses a catheter having a shaft 14 that has two configurations, namely, an original configuration as depicted in FIG. 12, and a deformed configuration as depicted in FIG. 11. The original configuration includes a large drainage lumen 35 having a circular cross section, but does not include a guideway providing transverse access from the catheter shaft exterior to the lumen 35. The deformed configuration is a compressed configuration wherein the lumen 35 is collapsed and the shaft as a whole is folded in on itself. The deformed configuration is an unstable configuration since the shaft is molded or otherwise predisposed to return to its original configuration. Thus, a stylet 12 or other gripping mechanism is required to hold the shaft in the deformed configuration.

The Examiner cites the Fuqua catheter in its unstable, deformed configuration as anticipating claims 20 and 21. The Examiner considers the fold 15 produced by folding the catheter shaft on itself as producing both a lumen and a guideway providing transverse access from the catheter shaft exterior to the lumen. This interpretation of the embodiment disclosed by Fuqua is respectfully traversed at least because Fuqua does not disclose how large the fold interior is with relation to a guidewire, and there is consequently no teaching or suggestion in Fuqua that the fold is sized to receive a guidewire. Furthermore, it is not clear from reading Fuqua that the distorted configuration, and the fold 15 produced thereby, extends along the entire catheter length from its proximal end to its distal end. For at least these reasons, claims 20 and 21 are not anticipated by Fuqua. Furthermore, in order to fully differentiate claim 20 from Fuqua, the claim is amended to recite that the catheter of the present invention has a single stable configuration in which the catheter is undefomed, and that the lumen and guideway providing transverse access thereto are included in the catheter design when it is in the single

stable and undeformed configuration. As previously discussed, the catheter has two configurations, and the only configuration that includes the fold 15 is a deformed configuration that is unstable. In view of these differences, the rejections of claims 20 and 21 should be withdrawn.

Claims 20 to 24 are rejected as being unpatentable over U.S. Patent No. 4,401,433 (Luther) in view of Fuqua. These rejections are respectfully traversed.

Luther discloses a method for folding a catheter to reduce its profile before inserting it into a vein. Viewing FIGs. 2A and 2B, the catheter assumes a substantially annular cross sectional configuration 20 when the catheter is in its stable, unfolded configuration. Deforming the catheter by folding it with a compressing apparatus brings the catheter to a deformed and unstable configuration 13, meaning that the catheter will return to assume its stable and unfolded configuration 20 when relieved of folding forces that produce the cross-sectional shape 13. The Examiner considers the fold produced by folding the catheter shaft on itself as producing both a lumen and a guideway providing transverse access from the catheter shaft exterior to the lumen.

The previously discussed deficiencies of Fuqua with respect to the presently amended claim 20 are not compensated for by Luther. Claim 20 as amended recites that the catheter of the present invention has a single stable configuration in which the catheter is undeformed, and that the lumen and guideway providing transverse access thereto are included in the catheter design when it is in the single stable and undeformed configuration. As previously discussed, the catheters disclosed by both Luther and Fuqua have at least two configurations, and the only configuration that includes a fold is a deformed configuration that is unstable. A person of ordinary skill in the relevant art would not find motivation from Fuqua and Luther to produce a catheter that has a single stable and undeformed configuration with a guidewire lumen and a guideway providing transverse access thereto from the catheter exterior since both Fuqua and Luther disclose catheters in which it is necessary for the catheters to assume a stable and unfolded condition during use. For at least these reasons, the rejections of claims 20 to 24 should be withdrawn.

Claims 13 to 19 are rejected as being anticipated by U.S. Patent No. 5,346,498 (Greelis). These rejections are respectfully traversed in view of the present amendment.

Independent claim 13 recites an elongate housing having an opening that extends from the housing proximal end to the distal end, and that is adapted to house both a catheter and a guidewire. The claim further recites that *a single wheel* is secured in a wheel port that is in communication with the opening so the single wheel can, by itself and upon rotation thereof, engage with a catheter that is housed in the opening. In contrast, Greelis discloses a housing 55 that includes an opening (passage 57) that is "adapted to receive [an] instrument 19" (col. 8, lines 15 to 19). Two wheels 81 and 83 are introduced into the opening, and both are required to advance or retract the instrument 19 therethrough. Although Greelis uses broad language when describing the type of instruments that may be advanced and retracted using two wheels ("virtually any elongated flexible instrument for medical purposes" - col. 8, lines 1 to 4), it is clear from reviewing the drawings and the supporting specification that the apparatus Greelis discloses is only constructed to advance wire-like instruments into a catheter, and consequently requires two opposing wheels to engage with such instruments. Since Greelis fails to teach or suggest an apparatus that is capable of engaging with and advancing or retracting a catheter using a single wheel by itself, Greelis clearly fails to anticipate claims 13 to 19 and the rejections of these claims should be withdrawn.

Claims 1 to 11 are rejected as being unpatentable over Luther in view of Fuqua and Greelis. Further, claims 1 to 2, and 6 to 11 are rejected as being unpatentable over Fuqua in view of Greelis. Finally, claims 1, and 6 to 12 are rejected as being unpatentable over Windheuser in view of Greelis. These rejections are respectfully traversed at least in view of the previous discussion regarding the rejections of independent claim 20.

Independent claim 1 is directed to a catheter guiding assembly that includes the catheter having the same features as those recited in claim 20. As previously discussed, Windheuser, Fuqua and Luther fail to disclose each and every feature of the catheter as presently claimed. Greelis fails to compensate for the deficiencies of Windheuser, Fuqua and Luther since Greelis does not disclose any particular structure for a catheter other than to describe the catheter as an elongate tubular body 21 that is attached to a distal end of a guidewire advancing apparatus 53. Greelis clearly fails to disclose a catheter having a catheter shaft having a first lumen that is sized to receive a guidewire, and a guideway providing transverse access from the catheter shaft exterior to the first lumen, wherein both the first lumen and the guideway extend the entire shaft

length, or more particularly, from the shaft proximal end to the shaft distal end. Further, Greelis clearly fails to disclose a catheter having a single stable configuration in which the catheter is undeformed, and that the lumen and guideway providing transverse access thereto are included in the catheter design when it is in the single stable and undeformed configuration. For at least these reasons, the rejections of claims 1 to 11 should be withdrawn.

F. Double Patenting

Claims 20 to 24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, and 12 to 15 of co-pending U.S. Application No. 10/903,802. The provisional rejection is noted. It is noted that the present amendment may substantially differentiate the claims from those of 10/903,802. Furthermore, if the present application is to issue before 10/903,802, it is expected that the provisional rejection of claims 20 to 24 of the present application will be withdrawn.

G. Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-0221.

Respectfully submitted,

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